

EXHIBIT 1

Message

From: kmay@restorerobotics.com [kmay@restorerobotics.com]
Sent: 7/21/2020 12:08:23 PM
To: 'Virani, Jitendra' [Jitendra.Virani@fda.hhs.gov]
CC: 'An, Je Hi' [Je.An@fda.hhs.gov]
Subject: jjRE: Restore Robotics -- Request for More Information

CDR Virani,

Restore intends to maintain the disclaimer. Restore has done robot service and instrument repair in the past and wants to ensure its customers associate its prior services relating to surgical robots and robotic instruments, including the quality and costs, with Restore Robotics alone. Customers hired Restore as an independent service organization, and Restore does not want its customers to think that the original equipment manufacturer Intuitive Surgical played any role in having provided the independent third-party services offered by Restore.

I hope this rationale satisfies your concern.

Regards,

Kevin

Kevin May
Restore Robotics
www.restorerobotics.com
kmay@restorerobotics.com

C 714-349-9015



From: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>
Sent: Monday, July 20, 2020 6:39 PM
To: kmay@restorerobotics.com
Cc: An, Je Hi <Je.An@fda.hhs.gov>
Subject: RE: Restore Robotics -- Request for More Information

Thank you Kevin for the update with your below email. We noticed that you have the following statement on your website: "da Vinci® and Intuitive® are registered trademarks of Intuitive Corporation. Restore Robotics is not affiliated with Intuitive®." Based on the information you provided with your below email, we do not think this statement is relevant on your website. Can you please update your website to remove this statement or provide your rationale on why it is needed?

Thanks.
Jit

From: kmay@restorerobotics.com <kmay@restorerobotics.com>
Sent: Friday, June 12, 2020 4:27 PM
To: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>

Cc: An, Je Hi <Je.An@fda.hhs.gov>

Subject: RE: Restore Robotics -- Request for More Information

CDR Virani,

Thank you for your patience during these difficult times. In response to your questions, let me formally confirm that Restore Robotics has indefinitely ceased its robotics repair services for business reasons that predate the pandemic. We will notify you of any change in circumstances.

Regards,

Kevin

Kevin May

Restore Robotics

www.restorerobotics.com

kmay@restorerobotics.com

C 714-349-9015



From: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>

Sent: Thursday, May 14, 2020 12:17 PM

To: kmay@restorerobotics.com

Cc: An, Je Hi <Je.An@fda.hhs.gov>

Subject: RE: Restore Robotics -- Request for More Information

Thank you Kevin for the update.

Jit

From: kmay@restorerobotics.com <kmay@restorerobotics.com>

Sent: Thursday, May 14, 2020 2:58 PM

To: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>

Cc: An, Je Hi <Je.An@fda.hhs.gov>

Subject: RE: Restore Robotics -- Request for More Information

CDR Virani,

We are still focused on helping to provide PPE for the Covid-19 crisis.

We have ceased all repair of Robotic systems and endowrist instruments. We do not know when we will re-start repairing Robotic Systems or endowrist instruments.

I will meet with the CEO and team to provide schedule for formal response in the coming week.

Kevin May

Restore Robotics

www.restorerobotics.com

kmay@restorerobotics.com

C 714-349-9015



From: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>

Sent: Thursday, May 14, 2020 11:06 AM

To: kmay@restorerobotics.com

Cc: An, Je Hi <Je.An@fda.hhs.gov>

Subject: RE: Restore Robotics -- Request for More Information

Hi Kevin,

Hope you are doing well and keeping it safe.

I wanted to touch base with you and see if you have an estimate on when might you be able to get back to us with your response to our questions?

Thanks.

Jit

From: kmay@restorerobotics.com <kmay@restorerobotics.com>

Sent: Friday, March 20, 2020 12:58 AM

To: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>

Cc: An, Je Hi <Je.An@fda.hhs.gov>

Subject: RE: Restore Robotics -- Request for More Information

CDR Virani,

Our CEO and our entire staff is working only on two items right now: finding Ventilators for hospitals and PPE equipment for hospitals. This is something we cannot deviate from right now. Can we take a few weeks to get back to you? Because of this crisis we are not doing any other work.

My apologies for the delay.

Kevin May

Restore Robotics

www.restorerobotics.com

kmay@restorerobotics.com

C 714-349-9015



From: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>
Sent: Monday, March 16, 2020 6:22 AM
To: kmay@restorerobotics.com
Cc: An, Je Hi <Je.An@fda.hhs.gov>
Subject: RE: Restore Robotics -- Request for More Information

Thank you Kevin for the update.

Sincerely,

CDR Jitendra Virani
Team Lead

Robotic Assisted Surgical Devices Team
DHT4A: Division of General Surgical Devices | OHT4: Office of Surgical and Infection Control Devices | Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. G456 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-6398
jitendra.virani@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: <https://www.research.net/s/cdrhcustomerservice?ID=1611&S=E>

From: kmay@restorerobotics.com <kmay@restorerobotics.com>
Sent: Monday, March 16, 2020 12:17 AM
To: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>
Cc: An, Je Hi <Je.An@fda.hhs.gov>
Subject: RE: Restore Robotics -- Request for More Information

CDR Virani,
We have met with our regulatory consultants and are working on our response.
I need to get our CEO Cliff Parker involved in our response. He has been extremely busy, as we are working on travel, work issues, taking care of our hospitals in this time of need and crafting company policy regarding the Covid-19 pandemic.
I will do my best to have a target date for you later this week.

Best Regards,

Kevin

Kevin May
Restore Robotics
www.restorerobotics.com

kmay@restorerobotics.com

C 714-349-9015



From: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>
Sent: Wednesday, March 11, 2020 11:12 AM
To: kmay@restorerobotics.com
Cc: An, Je Hi <Je.An@fda.hhs.gov>
Subject: RE: Restore Robotics -- Request for More Information

Thank you Kevin for the update.

Sincerely,

CDR Jitendra Virani
Team Lead

Robotic Assisted Surgical Devices Team
DHT4A: Division of General Surgical Devices | OHT4: Office of Surgical and Infection Control Devices | Office of Product Evaluation and Quality

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From: kmay@restorerobotics.com <kmay@restorerobotics.com>
Sent: Wednesday, March 11, 2020 1:59 PM
To: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>
Cc: An, Je Hi <Je.An@fda.hhs.gov>
Subject: RE: Restore Robotics -- Request for More Information

CDR Virani,

We are a very small company. We are meeting with our Regulatory consultant tomorrow. We will provide you a target date by this Friday.

Best Regards,

Kevin

Kevin May
Restore Robotics
www.restorerobotics.com
kmay@restorerobotics.com

C 714-349-9015



From: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 11:31 AM
To: kmay@restorerobotics.com
Cc: An, Je Hi <Je.An@fda.hhs.gov>
Subject: RE: Restore Robotics -- Request for More Information

Thank you Kevin. Can you please provide an estimate on date by which you can provide us with the requested information?

Thanks.
Jit

CDR Jitendra Virani
Team Lead

Robotic Assisted Surgical Devices Team
DHT4A: Division of General Surgical Devices | OHT4: Office of Surgical and Infection Control Devices | Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. G456 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-6398
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From: kmay@restorerobotics.com <kmay@restorerobotics.com>
Sent: Monday, March 9, 2020 3:06 PM
To: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>
Subject: RE: Restore Robotics -- Request for More Information

Dear CDR Virani,

We have received your email and we are working on our response to satisfy your inquiries .

Best regards,

Kevin

Kevin May

Restore Robotics

www.restorerobotics.com

kmay@restorerobotics.com

C 714-349-9015



From: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>

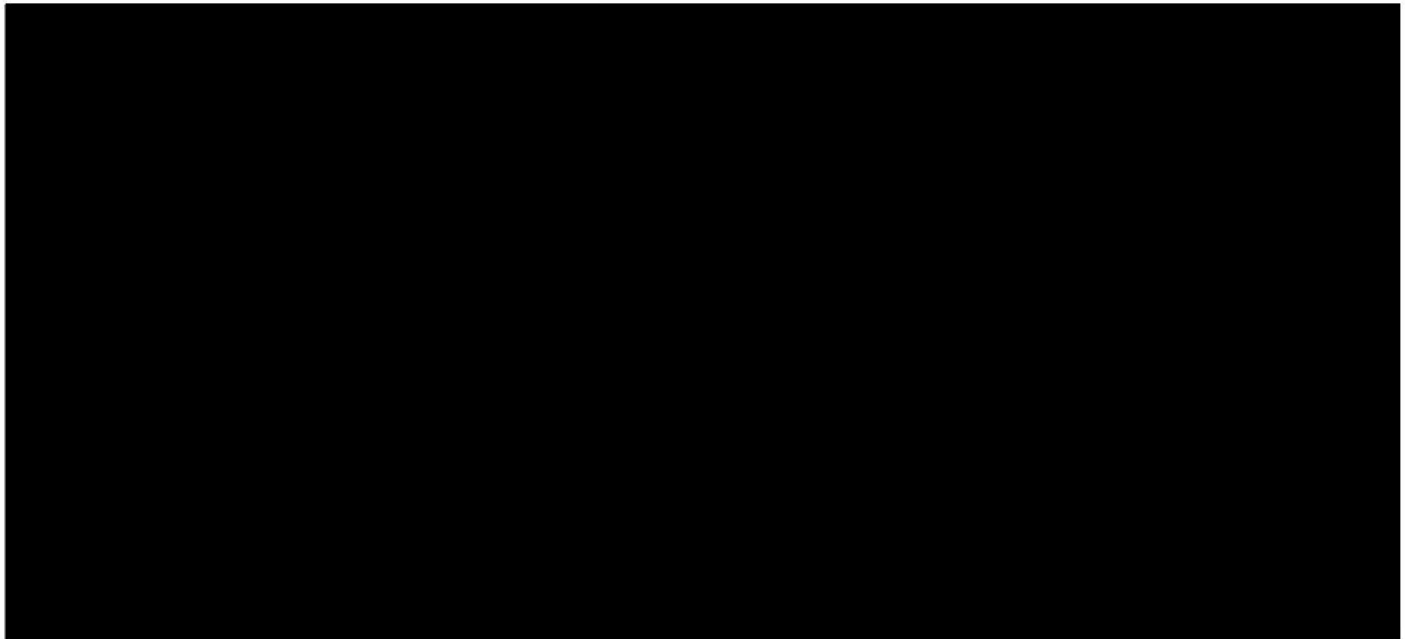
Sent: Thursday, March 05, 2020 10:46 AM

To: kmay@restorerobotics.com

Subject: Restore Robotics -- Request for More Information

Dear Kevin,

My name is CDR Jitendra Virani and moving forward I will be your FDA contact person for the issues being discussed in the below email chain.



Thank you for continuing to work with us. We look forward to your responses and are happy to discuss any clarifications if needed.

Sincerely,

CDR Jitendra Virani

Team Lead

Robotic Assisted Surgical Devices Team

DHT4A: Division of General Surgical Devices | OHT4: Office of Surgical and Infection Control Devices | Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. G456 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-6398

jitendra.virani@fda.hhs.gov

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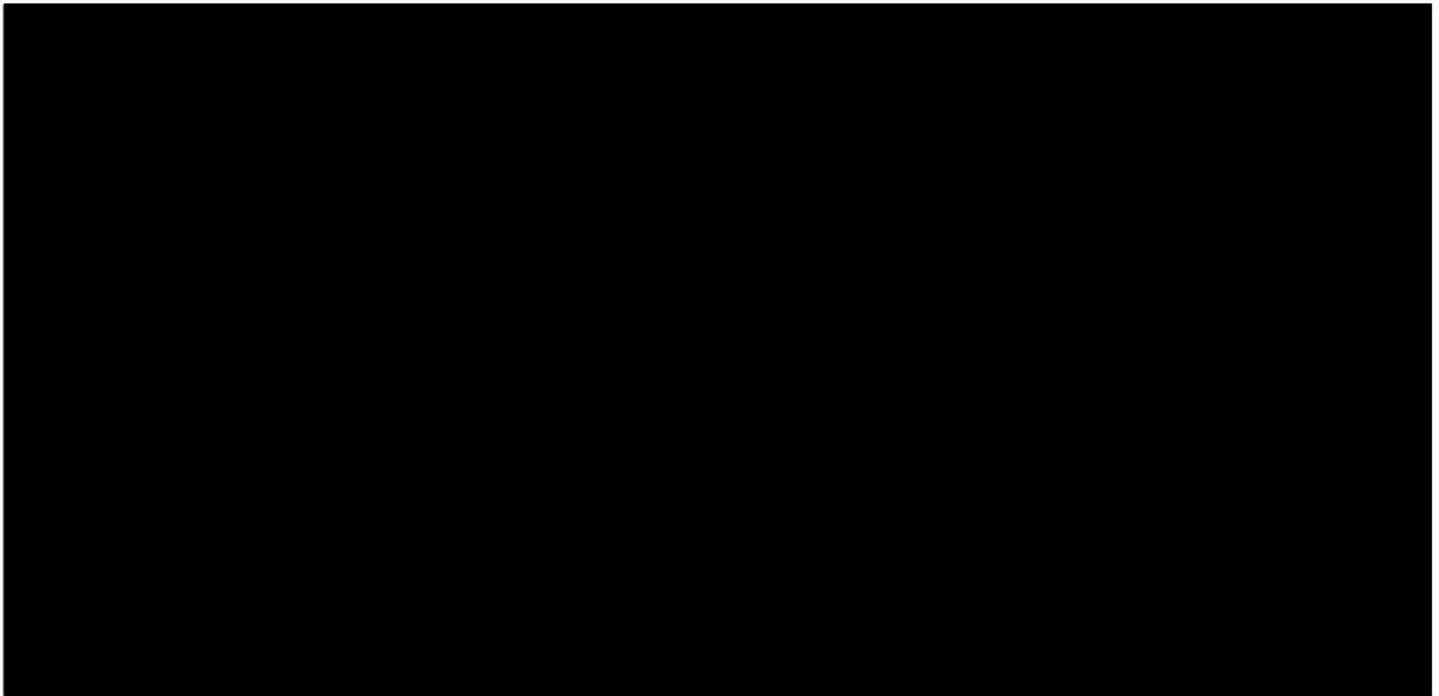
From: kmay@restorerobotics.com <kmay@restorerobotics.com>

Sent: Thursday, February 27, 2020 4:31 PM

To: An, Je Hi <Je.An@fda.hhs.gov>

Subject: RE: Follow up from FDA

Dr. An,



Let me know if you have any additional questions.

Regards,

Kevin

Kevin May

Restore Robotics

www.restorerobotics.com

kmay@restorerobotics.com

C 714-349-9015



From: An, Je Hi <Je.An@fda.hhs.gov>
Sent: Thursday, February 20, 2020 11:44 AM
To: kmay@restorerobotics.com
Subject: Follow up from FDA

Dear Mr. May,

We spoke on the phone today regarding Restore Robotics' activities and I wanted to follow up with you via email to summarize our conversation.

You state on your website www.restorerobotics.com that you restore robotic instruments and extend the lives of these instruments than the intended limit. Based on this information, we believe that a 510(k) is needed before you continue your operation.

You stated that you would provide within a week from today further description of your activities (for example, restoration of instruments) and an explanation of why a 510(k) is not needed.

Should you have any questions, please contact me.

Thank you,

Je Hi

Je Hi An, Ph.D.
Biomedical Engineer

Robotic Assisted Surgery Devices Team
DHT4A: Division of General Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration

Tel: 240-402-0018
JeHi.An@fda.hhs.gov



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